4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2013-N-0402]

Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing that will provide an overview of the current status of regulatory science initiatives for generic drugs and an opportunity for public input on research priorities in this area. FDA is seeking this input from a variety of stakeholders--industry, academia, patient advocates, professional societies, and other interested parties--as it fulfills its commitment under the Generic Drug User Fee Amendments of 2012 (GDUFA) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public hearing into account in developing the fiscal year (FY) 2015 Regulatory Science Plan.

DATES: The public hearing will be held on May 16, 2014, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security

information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Thushi Amini, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., MPN-1, rm. 1444, Rockville, MD 20855, 240-276-8810, email: Thushi.Amini@fda.hhs.gov; or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., MPN-1, rm. 1449, Rockville, MD 20855, 240-276-8619, email: Robert.Lionberger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Registration and Requests for Oral Presentations: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by Webcast (see Streaming Webcast of the Public Hearing)) and/or present at the hearing, please register for the hearing and/or make a request for oral presentations or comments by email to GDUFARegulatoryScience@fda.hhs.gov by April 25, 2014. The email should contain complete contact information for each attendee (i.e., name, title, affiliation, address, email address, and telephone number). Those without email access can register by contacting Thushi Amini by April 25, 2014 (see Contact Person).

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the topic, or topics, they wish to address (see section IV). This will help FDA organize the presentations. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak. Once FDA notifies registered presenters of their

scheduled times, they are encouraged to submit an electronic copy of their presentation to GDUFARegulatoryScience@fda.hhs.gov on or before May 9, 2014. Persons registered to make an oral presentation are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the hearing and other background materials will be made available 5 days before the hearing at http://www.fda.gov/Drugs/NewsEvents/ucm344710.htm.

If you need special accommodations because of a disability, please contact Thushi Amini (see Contact Person) at least 7 days before the hearing.

Streaming Webcast of the Public Hearing: For those unable to attend in person, FDA will provide a live Webcast of the hearing. To join the hearing via the Webcast, please go to https://collaboration.fda.gov/regscipart15/.

Comments: Regardless of attendance at the public hearing, interested persons may submit either electronic comments to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), 5600 Fishers Lane, rm. 1061, Rockville, MD 20857. The deadline for submitting comments to the docket is June 13, 2014. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may also be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to

the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

I. Background

In July 2012, Congress passed GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144)). GDUFA is designed to enhance public access to safe, high-quality generic drugs and reduce costs to industry. To support this goal, FDA agreed in the GDUFA commitment letter to work with industry and interested stakeholders on identifying regulatory science research priorities specific to generic drugs for each fiscal year covered by GDUFA. The commitment letter outlines FDA's performance goals and procedures under the GDUFA program for the years 2012-2017. The commitment letter can be found at http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.

II. FY 2013 Regulatory Science Priorities

The FY 2013 regulatory science research priorities list was developed by FDA and industry and included in the GDUFA commitment letter. To implement the FY 2013 priorities list, the Office of Generic Drugs awarded $17 million in external contracts and grants to initiate new research studies during FY 2013. Four million dollars were allocated to support internal research related to generic drugs. This includes rapid response capabilities through equipment for FDA labs and support for laboratory research fellows at FDA, as well as research fellows to work on data analysis and coordination of internal activities with external grants and contracts.

III. FY 2014 Regulatory Science Priorities

On June 21, 2013, the Office of Generic Drugs held a public hearing to gain input in developing the FY 2014 regulatory science priorities list. This list was prepared based on

internal Center for Drug Evaluation and Research discussions, comments received from this public hearing, and comments submitted to the public docket.

The FY 2014 Regulatory Science Priorities are as follows:

1. Postmarket evaluation of generic drugs,
2. Equivalence of complex products,
3. Equivalence of locally acting products,
4. Therapeutic equivalence evaluation and standards, and
5. Computational and analytical tools.

For more information on these topic areas, please visit http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm370952.htm.

IV. Purpose and Scope of the May 16, 2014, Public Hearing

The purpose of the May 2014 public hearing is to obtain input from industry and other interested stakeholders on the identification of regulatory science priorities for FY 2015. To help fulfill FDA's mission, FDA is particularly interested in receiving input on the following topics:

1. Current regulatory science challenges that limit the availability of generic drugs,
2. Regulatory science approaches to improve the preapproval evaluation of therapeutic equivalence of generic drugs,
3. Postapproval regulatory science approaches to ensure the therapeutic equivalence of approved generic drugs,
4. Prioritization of FY 2015 regulatory science research topics for generic drugs based on public health impact, and
5. The need for additional or revised draft guidance to clarify FDA's scientific recommendations related to generic drug development.

FDA will consider all comments made at this hearing or received through the docket (see Comments) as it develops its FY 2015 GDUFA Regulatory Science Plan. Additional information concerning GDUFA, including the text of the law and the commitment letter can be found on the FDA Web site at http://www.fda.gov/gdufa.

V. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research. Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may pose questions; they may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C) (21 CFR part 10, subpart C)). Under § 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see Transcripts). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: February 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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